

USSN: 09/011,940
Amdt. Dated January 12, 2004
Reply to Office Action of November 10, 2003
Page 7 of 11

REMARKS

As a preliminary matter, Applicants thank the Examiner for noting the discrepancy between claim 46 prior to the September 2, 2003 Response and claim 46 as it appeared in the September 2, 2003 Response. It was not Applicants' intent to change claim 46 in the previous Response. Accordingly, while no claim amendment is being made in the instant Response, the claims have been included in this paper with claim 46 written as it appeared prior to the September 2, 2003 Response.

Claims 1, 17-19, 21, 23-25, 32-35, 41-46, and 48-55 are currently pending.

Applicants note with appreciation that the Patent Office has found claims 41-44, 48, 51, and 55 allowable over the prior art of record. Applicants respectfully submit that claims 1, 17-19, 21, 23-25, 32-35, 45, 46, 49, 50, and 52-54 are patentable as well for the following reasons.

Issues under 35 U.S.C. 102(b)

Claims 1, 17-19, 21, 23-25, 32, 35, 45, and 52-54 are rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Baer *et al.* Diabetes Vol. 34 (Nov. 1985) pages 1108-112 (hereinafter the "Baer" reference).

The Baer reference describes a study to explore the effects of long-term elevation of plasma GIP by looking at responses to parenteral and enteral alimentation in rats. In order to conduct their study, the authors provided weight-maintaining liquid diets to the rats with a subset receiving GIP. The study showed that GIP appeared to induce hyperinsulinemia with insulin resistance during parenteral alimentation, (a mean plasma glucose level of 184 ± 9 mg/dl), as opposed to parenteral alimentation without GIP (a mean plasma glucose level of 126 ± 3 mg/dl). Thus, there is an increase in plasma glucose levels when GIP is administered.

In the present invention, it should be remembered that the invention is more than providing parenteral nutrition; instead, the claimed invention is directed to providing enhanced parenteral nutrition that will allow higher levels of nutrition while avoiding negative side effects

USSN: 09/011,940
Amdt. Dated January 12, 2004
Reply to Office Action of November 10, 2003
Page 8 of 11

such as inducing hyperglycemia. The claimed invention does this by administering the parenterally delivered nutrient with at least one insulintropic peptide.

The Baer reference fails to properly teach each and every element of the claimed invention for at least two reasons. First, Baer only teaches using parenteral and enteral alimentation as a way to study the long-term effects GIP. It does not teach the use of parenteral administration of nutrients and an insulintropic peptide as a treatment. It does not teach or suggest the usefulness of administering a nutritively effective amount of nutrients with an insulintropic peptide to treat a patient in need of parenteral nutrition. Second, based upon the findings, Baer would teach away from administering a nutritively effective amount of nutrients with an insulintropic peptide to treat a patient in need of parenteral nutrition as Baer shows that GIP causes a deleterious rise in the plasma blood glucose level when administered with parenteral alimentation (see, for example, Figure 1 in Baer). This effect is something that the instant invention is designed to avoid. Thus, in spite of what is disclosed in Baer, the inventors have recognized and claimed a treatment including the parenteral administration of nutrients and an insulintropic peptide.

Accordingly, Applicants respectfully submit that for the reasons provided above, Baer does not teach each and every element of the claimed invention and request reconsideration and withdrawal of the rejection based upon Baer under 35 U.S.C. 102(b).

Claims 1, 17-19, 21, 23-25, 32, 35, 45, and 52-54 are rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Amland *et al.* Scandinavian Journal of Gastroenterology, Vol. 20, No. 3 (April 1985) pages 321-324 (hereinafter the "Amland" reference).

Amland teaches the use of an infusion of GIP and glucose to study the effects of atropine on GIP-induced insulin and pancreatic polypeptide release in man. Like the use contemplated in Baer, Amland teaches the infusion of GIP and a nutrient as a mechanism for experimental research; however, it does not teach the use of nutrients and an insulintropic peptide in the treatment of patients. For example, Amland does not contemplate the benefits of parenteral nutrition with GIP as opposed to parenteral nutrition without GIP. Thus, there is no teaching in

USSN: 09/011,940
Amdt. Dated January 12, 2004
Reply to Office Action of November 10, 2003
Page 9 of 11

Amland that delivery of parenteral nutrition can be enhanced by the administration of an insulintropic peptide. As such, Amland cannot be fairly said to teach or suggest a treatment that includes the parenteral administration of nutrients and an insulintropic peptide.

Accordingly, Applicants respectfully submit that Amland does not teach each and every element of the claimed invention and request reconsideration and withdrawal of the rejection based upon Amland under 35 U.S.C. 102(b).

Issues under 35 U.S.C. 102(e)

Claims 1, 17-19, 21, 23-25, 32-35, 45, 46, and 52-54 are rejected under 35 U.S.C. 102(e) for allegedly being anticipated by U.S. Patent No. 5,614,492 to Habener (hereinafter the "Habener" reference).

Habener describes certain peptide fragments of the prohormone proglucagon (such as GLP-1 (7-36)) that are purported to possess hormonal activities and that can be used to stimulate the synthesis and secretion of the hormone, insulin.

Habener, however, does not teach providing parenteral nutrition by administering a nutritively effective amount of nutrients with an insulintropic peptide. Applicants further submit that Habener did not even contemplate providing parenteral nutrition, as parenteral nutrition is not mentioned in the reference. In fact, Example 11 shows that when nutrition with GLP-1 was contemplated, it was with a standard breakfast meal and not a parenteral nutrient administration. The body's response to an enteral administration of nutrient differs from its response to parenteral administration of nutrient. Accordingly, Habener does not teach or suggest a treatment that includes the parenteral administration of nutrients and an insulintropic peptide.

Accordingly, for the reasons provided above, Applicants respectfully submit that Habener does not teach each and every element of the claimed invention and request reconsideration and withdrawal of the rejection based upon Habener under 35 U.S.C. 102(e).

USSN: 09/011,940
Amdt. Dated January 12, 2004
Reply to Office Action of November 10, 2003
Page 10 of 11

Issues under 35 U.S.C. 103(a)

Claims 1, 17-19, 21, 23-25, 32-35, 45, 46, 49-50, and 52-54 are rejected under 35 U.S.C. 103(a) for allegedly being unpatentable over the Specification in view of Habener and/or U.S. Patent No. 5,424,286 to Eng (hereinafter the "Eng" reference).

Eng describes the use of exendin-3 or exendin-4 and fragments thereof for treating diabetes mellitus and preventing hyperglycemia. Eng does not teach providing a treatment based upon delivery of parenteral nutrition.

The Patent Office alleges Habener and/or Eng describes lowering of meal-related glucose levels by parenteral administration of GLP-1 and other "insulinotropic" peptides alone or in combination with GLP-1 (see page 6, lines 6-14, of the Office Action). However, Applicants respectfully submit that neither Habener nor Eng teaches providing a treatment for delivering parenteral nutrition including a nutritively effective amount of nutrients and at least one insulinotropic peptide.

The Patent Office further alleges that one of ordinary skill in the art would be motivated to substitute the "insulinotropic peptides" disclosed by Eng or Habener for insulin in "parenteral" formulations as disclosed in the Specification (see page 6, last paragraph carried over to page 7, of the Office Action). Applicants, however, respectfully submit that the Patent Office is using impermissible hindsight based upon Applicants' own disclosure as a basis for rejecting the claims.

It was the instant inventors who first recognized that more nutrients can be delivered parenterally with the administration of an insulinotropic peptide; thereby, discovering a new, desirable treatment for providing parenteral nutrition. It should be noted that neither Eng nor Habener teaches, suggests, or motivates one of ordinary skill in the art to provide parenteral nutrition as in the claimed invention. In other words, neither discusses the use of parenteral nutrition as a form of treatment. Moreover, while many references, including Baer and Amland as discussed, have used parenteral administration of a nutrient for studies involving

USSN: 09/011,940

Amtd. Dated January 12, 2004

Reply to Office Action of November 10, 2003

Page 11 of 11

insulinotropic peptides, none have recognized the benefit of using parenteral delivery of nutrients and insulinotropic peptides as a method of treatment, as used in the instant invention.

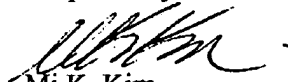
Accordingly, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art, absent the instant disclosure, the benefits of providing a treatment that includes the parenteral administration of nutrients and an insulinotropic peptide. Thus, Applicants respectfully submit that the claimed invention is not unpatentable over the Specification in view of Eng and/or Habener and request reconsideration and withdrawal of the rejection based upon 35 U.S.C. 103(a).

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance. The Examiner is encouraged to call the undersigned attorney to discuss any issues related to the prosecution of the instant application.

Applicants believe that no fee is necessitated by the present paper. However, in the event any fees are due or any amount is to be credited, Applicants authorize the Commissioner of Patents to debit or credit Deposit Account No. 01-0535.

Respectfully submitted,



Mi K. Kim
Reg. No. 44, 830

AMYLIN PHARMACEUTICALS, INC.
9360 Towne Centre Drive, Suite 110
San Diego, CA 92121
Phone: (858) 552-2200
Facsimile: (858) 552-1936